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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,220	06/08/2001	Karin Westlund High	265.0019 0101	8535

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 01/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,220

Applicant(s)

High et al.

Examiner

Michael Brannock

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 30, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) 1-19, 22, 23, and 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 21, 24, and 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jun 8, 2001 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

Art Unit: 1646

DETAILED ACTION

Status of Application: Claims and Amendments

1. Claims 1-31 are pending.
2. Applicant is notified that the amendments put forth in Paper 5, 5/21/02, have been entered in full.
3. Claims 1-19, 22, 23 and 25-28 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8, 10/30/02.
4. Applicant's election with traverse of Group II, claims 20, 21, 24, 29-31 in Paper 8 is acknowledged. The traversal is on the grounds that a search of Groups I-III would not be a serious burden on the examiner. This is not found persuasive for the following reasons:

Under MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 8702.01, 806.04, 808.01) **or** distinct as claimed (see MPEP § 806.05- §806.05(I)): and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a)- 806.04(I), § 808.01(a), and § 808.02).

Art Unit: 1646

Consistent with current patent practice, a serious search burden may be established by (A) separate classification thereof; (B) a separate status in the art when they are classifiable together; (C) a different field of search. These criteria were met in the above restriction. Further, a search is directed not only to art which would be anticipatory, but also to art that would render the invention obvious. In the instant case, the methods of groups I and III involve goals that are distinct from each other and from the goals set forth in elected group II. The methods of each group require separate starting materials and accomplish divergent goals; although a search of the methods of elected group II would overlap a search of the methods of groups I and III, the three searches would not be coextensive, and to search all three inventions in a single application would be unduly burdensome. Therefore, the restriction is maintained and made final.

Drawings

5. The drawings are objected to as set forth in the attached PTO-948. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1646

6. Claim 29 recites the limitation "the compound" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim, thus the artisan would not know which compound is "the compound".

7. Claims 20, 21, 24, 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims claim methods for identifying compounds comprising a step or steps that require that the artisan use "an effective amount of the compound", yet the claims do not specifically require that the "effective amount" be effective at any particular thing. The specification defines "effective amount" as an "amount effective to decrease or prevent in a subject the symptoms associated with a condition herein", see page 6, lines 21 and 22. However, because the claims do not specify what the amount is to be effective for, it is unclear if Applicant intends that the claims be limited to the use of only those amounts of a compound that are effective in the treatment of the recited conditions; thus the metes and bounds of the claims cannot be determined.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 20, 21, 24, 29-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

Art Unit: 1646

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims claim methods for identifying compounds comprising a step or steps that require that the artisan use “an effective amount of the compound”. Although the claims do not specifically require that the “effective amount” be effective at any particular thing, the specification defines “effective amount” as an “amount effective to decrease or prevent in a subject the symptoms associated with a condition herein”, see page 6, lines 21 and 22. The specification further lists a multitude of conditions, e.g. decrease in mental function, aging, memory disturbances, etc., see page 6, yet the specification provides no guidance as to an effective amount of any compound for any of these disparate conditions. Nor do such compounds appear to be recognized in the art. Thus, the claims require that the artisan be in possession of an effective amount of these compounds in order to practice the claimed invention. The specification merely provides an invitation to the highly skilled artisan to begin an extensive research plan of essentially random trial and error experimentation wherein different compounds are tested to try to find compounds that can be administered in “an effective amount” as defined by the specification. Such random trial and error experimentation would be unduly burdensome. It is suggested to Applicant that removal of the phrase “effective amount”, would obviate this rejection.

Art Unit: 1646

10. Claims 20, 21, 24, 29-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As set forth above, the claims require that the artisan be in possession of a compound in an "amount effective to decrease or prevent in a subject the symptoms associated with a condition herein". The specification provides general guidelines regarding pharmaceutical preparations, e.g. pg 20, yet the specification does not appear to assert that any particular amount is effective to treat any particular condition, nor could such information be reasonably inferred from the information provided in the specification. Thus the skilled artisan would not recognize that Applicant was in possession of the genus of compounds in an "amount effective to decrease or prevent in a subject the symptoms associated with a condition herein". It is suggested to Applicant that removal of the phrase "effective amount", would also obviate this rejection.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1646

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 20, 21, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Rao et al., Neuron, 19(801-812)1997.

As set forth above in item 6, the claims do not appear to require the "effective amount" of the compound be effective at any particular thing. Rao et al., disclose an assay that monitors NR1 subcellular distribution, comprising contacting the cell with an amount of a compound effective to alter the subcellular distribution of NR1, e.g. APV (see page 802), and activating an NMDA receptor (e.g. administering NMDA, see col 1, page 804), and detecting the distribution of NR1 in a neuron, e.g. see Figure 1.

Conclusion

13. No claims are allowable.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Marsh et al., J. Neurochemistry 77(23-33)2001

Hall and Soderling, J. Biol. Chem. 272(4135-4140)1997

Ehlers, et al., J. Neuroscience 18(2)720-730, 1998

Skeberdis, et al., PNAS 98(6)3561-3566, 2001


Art Unit: 1646

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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January 26, 2003